ARC 1793C

PHARMACY BOARD[657]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)*"b."*

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 6, "General Pharmacy Practice," Chapter 7, "Hospital Pharmacy Practice," Chapter 8, "Universal Practice Standards," Chapter 9, "Automated Medication Distribution Systems and Telepharmacy Services," Chapter 15, "Correctional Pharmacy Practice," Chapter 18, "Centralized Prescription Filling and Processing," Chapter 19, "Nonresident Pharmacy Practice," Chapter 22, "Unit Dose, Alternative Packaging, and Emergency Boxes," and Chapter 23, "Long-Term Care Pharmacy Practice," Iowa Administrative Code.

The amendments were approved at the November 19, 2014, regular meeting of the Board of Pharmacy.

The proposed amendments update and clarify the persons responsible for various activities required by Board rules including responsibilities shared by a pharmacy, by and through its owner or license holder, the pharmacist in charge (PIC), and staff pharmacists. The purpose for the proposed amendments is to assign responsibility for pharmacy activities and functions to the party or parties that have the ability to control those activities and functions. The proposed amendments are a result of recommendations made by the 2014 PIC Task Force. The PIC Task Force was established at the recommendation of the 2013 Patient Safety Task Force. In developing its recommendations to the Board, the PIC Task Force reviewed current Board rules and the rules and regulations of other state licensing authorities, in addition to discussing responsibility issues and current pharmacy management and practice issues and standards.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34.

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on January 15, 2015. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by e-mail to terry.witkowski@iowa.gov.

A public hearing will be held on January 15, 2015, at 9 a.m. in the shared conference room at the Board of Pharmacy Office, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa, for the purpose of receiving oral and written comments. Interested persons will be asked to give their names and addresses for the record and to confine their remarks to the subject of the amendments.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code sections 124.301, 126.11, 147.107, 155A.13, 155A.13A, 155A.15, 155A.19, and 155A.33.

The following amendments are proposed.

ITEM 1. Amend rule 657—6.2(155A) as follows:

657—6.2(155A) Pharmacist in charge. One professionally competent, legally qualified pharmacist in charge in each pharmacy shall be responsible for, at a minimum, ~~the following:~~ the responsibilities identified in rule 657—8.3(155A).

~~1. Ensuring that the pharmacy utilizes an ongoing, systematic program for achieving performance improvement and ensuring the quality of pharmaceutical services.~~

~~2. Ensuring that the pharmacy employs an adequate number of qualified personnel commensurate with the size and scope of services provided by the pharmacy.~~

~~3. Ensuring the availability of any equipment and references necessary for the particular practice of pharmacy.~~

~~4. Ensuring that a pharmacist performs prospective drug use review as specified in rule 657—8.21(155A).~~

~~5. Ensuring that a pharmacist provides patient counseling as specified in rule 657—6.14(155A).~~

~~6. Dispensing drugs to patients, including the packaging, preparation, compounding, and labeling functions performed by pharmacy personnel.~~

~~7. Delivering drugs to the patient or the patient's agent.~~

~~8. Ensuring that patient medication records are maintained as specified in rule 657—6.13(155A).~~

~~9. Training pharmacy technicians and pharmacy support persons.~~

~~10. Procuring and storing prescription drugs and devices and other products dispensed from the pharmacy.~~

~~11. Distributing and disposing of drugs from the pharmacy.~~

~~12. Maintaining records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all drugs as required by applicable state and federal laws, rules, and regulations.~~

~~13. Establishing and maintaining effective controls against the theft or diversion of prescription drugs and records for such drugs.~~

~~14. Establishing, implementing, and periodically reviewing and revising written policies and procedures to reflect changes in processes, organization, and other functions for all operations of the pharmacy and ensuring that all pharmacy personnel are familiar with those policies and procedures.~~

~~15. Ensuring the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy.~~

~~16. Ensuring that there is adequate space within the prescription department or a locked room not accessible to the public for the storage of prescription drugs, devices, and controlled substances and to support the operations of the pharmacy.~~

ITEM 2. Amend rule 657—7.2(155A) as follows:

657—7.2(155A) Pharmacist in charge. One professionally competent, legally qualified pharmacist in charge in each pharmacy shall be responsible for, at a minimum, the ~~items identified in this rule~~ responsibilities identified in rule 657—8.3(155A). ~~A part-time pharmacist in charge has the same obligations and responsibilities as a full-time pharmacist in charge.~~ Where 24-hour operation of the pharmacy is not feasible, a pharmacist shall be available on an "on call" basis. ~~The pharmacist in charge, at a minimum, shall be responsible for:~~

~~1. Ensuring that the pharmacy utilizes an ongoing, systematic program for achieving performance improvement and ensuring the quality of pharmaceutical services.~~

~~2. Ensuring that the pharmacy employs an adequate number of qualified personnel commensurate with the size and scope of services provided by the pharmacy and sufficient to ensure adequate levels of quality patient care services. Drug dispensing by nonpharmacists shall be minimized and eliminated wherever possible.~~

~~3. Ensuring the availability of any equipment and references necessary for the particular practice of pharmacy.~~

~~4. Ensuring that a pharmacist performs therapeutic drug monitoring and drug use evaluation.~~

~~5. Ensuring that a pharmacist provides drug information to other health professionals and to patients.~~

~~6. Dispensing drugs to patients, including the packaging, preparation, compounding, and labeling functions performed by pharmacy personnel.~~

~~7. Delivering drugs to the patient or the patient's agent.~~

~~8. Ensuring that patient medication records are maintained as specified in rule 657—7.10(124,155A).~~

~~9. Training pharmacy technicians and pharmacy support persons.~~

~~10. Ensuring adequate and appropriate pharmacist oversight and supervision of pharmacy technicians and pharmacy support persons.~~

~~11. Procuring and storing prescription drugs and devices and other products dispensed from the pharmacy.~~

~~12. Distributing and disposing of drugs from the pharmacy.~~

~~13. Maintaining records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all drugs as required by applicable state and federal laws, rules, and regulations.~~

~~14. Establishing and maintaining effective controls against the theft or diversion of prescription drugs, controlled substances, and records for such drugs.~~

~~15. Preparing a written operations manual governing pharmacy functions; periodically reviewing and revising those policies and procedures to reflect changes in processes, organization, and other pharmacy functions; and ensuring that all pharmacy personnel are familiar with the contents of the manual.~~

~~16. Ensuring the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy.~~

ITEM 3. Amend rule 657—7.8(124,126,155A) as follows:

657—7.8(124,126,155A) Drug distribution and control. Policies and procedures governing drug distribution and control shall be ~~developed by the pharmacist in charge~~ established pursuant to rule 657—8.3(155A) with input from other involved hospital staff such as physicians and nurses, from committees such as the pharmacy and therapeutics committee or its equivalent, and from any related patient care committee. It is essential that the pharmacist in charge or designee routinely be available to or on all patient care areas to establish rapport with the personnel and to become familiar with and contribute to medical and nursing procedures relating to drugs.

7.8(1) *Drug preparation.* ~~The pharmacist shall institute the control~~ Control and adequate quality assurance procedures needed to ensure that patients receive the correct drugs at the proper times shall be established pursuant to rule 657—8.3(155A). ~~Adequate quality assurance procedures shall be developed.~~

a. Hospitals shall utilize a unit dose dispensing system pursuant to rule 657—22.1(155A). All drugs dispensed by the ~~pharmacist~~ pharmacy for administration to patients shall be in single unit or unit dose packages if practicable unless the dosage form or drug delivery device makes it impracticable to package the drug in a unit dose or single unit package.

(1) ~~The pharmacist in charge shall establish~~ Established policies and procedures ~~that~~ shall identify situations when drugs may be dispensed in other than unit dose or single unit packages outside the unit dose dispensing system.

(2) The need for nurses to manipulate drugs prior to their administration shall be minimized.

b. Pharmacy personnel shall, except as specified in policies and procedures, prepare all sterile products in conformance with 657—Chapter ~~13~~ 20.

c. Pharmacy personnel shall compound or prepare drug formulations, strengths, dosage forms, and packages useful in the care of patients.

7.8(2) *Drug formulary.* ~~The pharmacist in charge shall maintain~~ Established policies and procedures shall include a current formulary of drug products approved for use in the institution and shall ~~be responsible for~~ include specifications for those drug products ~~and for selecting their source of supply~~.

7.8(3) to **7.8(6)** No change.

7.8(7) *Drugs brought into the institution.* ~~The pharmacist in charge~~ Established policies and procedures shall determine those circumstances when patient-owned drugs brought into the institution may be administered to a hospital patient and shall ~~establish policies and~~ identify procedures governing the use and security of drugs brought into the institution. Procedures shall address identification of the drug and methods for ensuring the integrity of the product prior to permitting its use by the patient. The use of patient-owned drugs shall be minimized to the greatest extent possible.

7.8(8) and **7.8(9)** No change.

7.8(10) *Hazardous drugs and chemicals.* ~~The pharmacist, in cooperation with other hospital staff, shall establish policies~~ Policies and procedures for handling drugs and chemicals that are known occupational hazards shall be established pursuant to rule 657—8.3(155A). The procedures shall maintain the integrity of the drug or chemical and protect hospital personnel.

7.8(11) *Leave meds.* Labeling of prescription drugs for a patient on leave from the facility for a period in excess of 24 hours shall comply with 657—subrule 6.10(1). The dispensing ~~pharmacy~~ pharmacist shall be responsible for packaging and labeling leave meds in compliance with this subrule.

7.8(12) *Discharge meds.* Drugs authorized for a patient being discharged from the facility shall be labeled in compliance with 657—subrule 6.10(1) before the patient removes those drugs from the facility premises. The dispensing ~~pharmacy~~ pharmacist shall be responsible for packaging and labeling discharge meds in compliance with this subrule.

7.8(13) *Own-use outpatient prescriptions.* If the hospital pharmacy dispenses own-use outpatient prescriptions, the ~~pharmacy~~ pharmacist shall comply with all requirements of 657—Chapter 6 except rule 657—6.1(155A).

7.8(14) No change.

ITEM 4. Amend rule 657—7.9(124,155A) as follows:

657—7.9(124,155A) Drug information. ~~The pharmacy is responsible for providing the institution's staff and patients with~~ Established policies and procedures shall include the provision to the institution's staff and patients of accurate, comprehensive information about drugs and their use ~~and shall serve as its center for drug information~~. The pharmacy shall serve as the institution's center for drug information.

7.9(1) and **7.9(2)** No change.

ITEM 5. Amend rule 657—7.10(124,155A) as follows:

657—7.10(124,155A) Ensuring rational drug therapy. An important aspect of pharmaceutical services is that of maximizing rational drug use. ~~The pharmacist, in concert with the medical staff, shall develop policies~~ Policies and procedures for ensuring the quality of drug therapy shall be established pursuant to rule 657—8.3(155A).

7.10(1) No change.

7.10(2) *Adverse drug events.* ~~The pharmacist, in cooperation with the appropriate patient care committee, shall develop~~ Established policies and procedures shall include a mechanism for the reporting and review, by the committee or other appropriate medical group, of adverse drug events. The pharmacist shall be informed of all reported adverse drug events occurring in the facility. Adverse drug events include but need not be limited to adverse drug reactions and medication errors.

ITEM 6. Amend rule 657—7.11(124,126,155A) as follows:

657—7.11(124,126,155A) Outpatient services. No prescription drugs shall be dispensed to patients in a hospital outpatient setting. If a need is established for the dispensing of a prescription drug to an outpatient, a prescription drug order shall be provided to the patient to be filled at a pharmacy of the patient's choice.

7.11(1) No change.

7.11(2) *Administration in the outpatient setting.* Drugs shall be administered only to outpatients who have been examined and evaluated by a prescriber who determined the patient's need for the drug therapy ordered.

a. Accountability. ~~A~~ Established policies and procedures shall include a system of drug control and accountability ~~shall be developed and supervised by the pharmacist in charge and the facility's outpatient services committee, or a similar group or person responsible for policy~~ in the outpatient setting. The system shall ensure accountability of drugs incidental to outpatient nonemergency therapy or treatment. Drugs shall be administered only in accordance with the system.

b. and *c.* No change.

ITEM 7. Amend rule 657—7.12(124,126,155A) as follows:

657—7.12(124,126,155A) Drugs in the emergency department. Drugs maintained in the emergency department are kept for use by or at the direction of prescribers in the emergency department. Drugs shall be administered or dispensed only to emergency department patients. For the purposes of this rule, "emergency department patient" means an individual who is examined and evaluated in the emergency department.

7.12(1) *Accountability.* ~~A~~ Established policies and procedures shall include a system of drug control and accountability ~~shall be developed and supervised by the pharmacist in charge and the facility's emergency department committee, or a similar group or person responsible for policy~~ in the emergency department. The system shall identify drugs of the nature and type to meet the immediate needs of emergency department patients. Drugs shall be administered or dispensed only in accordance with the system.

7.12(2) No change.

7.12(3) *Drug dispensing.* In those facilities with 24-hour pharmacy services, only a pharmacist or prescriber may dispense any drugs to an emergency department patient. In those facilities located in an area of the state where 24-hour outpatient or 24-hour on-call pharmacy services are not available within 15 miles of the hospital, and which facilities are without 24-hour outpatient pharmacy services, the provisions of this rule shall apply.

a. ~~*Pharmacist in charge responsibility*~~ *Responsibility.* ~~The pharmacist in charge is responsible for maintaining~~ Pursuant to rule 657—8.3(155A), the accuracy and labeling of prepackaged drugs shall be ensured and accurate records of dispensing of drugs from the emergency department ~~and for ensuring the accuracy of prepackaged drugs and the complete and accurate labeling of prepackaged drugs pursuant to this paragraph~~ shall be maintained.

(1) and (2) No change.

b. No change.

7.12(4) No change.

ITEM 8. Amend rule 657—8.3(155A) as follows:

657—8.3(155A) ~~Responsibility~~ Responsible parties.

~~8.3(1)~~ ~~*Pharmacy operations.* The pharmacy and the pharmacist in charge share responsibility for ensuring that all operations of the pharmacy are in compliance with federal and state laws, rules, and regulations relating to pharmacy operations and the practice of pharmacy.~~

8.3(1) *Pharmacist in charge.* One professionally competent, legally qualified pharmacist in charge in each pharmacy shall work cooperatively with the pharmacy, by and through its owner or license holder, and with all staff pharmacists to ensure the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy. A part-time pharmacist in charge has the same obligations and responsibilities as a full-time pharmacist in charge.

8.3(2) *Pharmacy.* Each pharmacy, by and through its owner or license holder, shall work cooperatively with the pharmacist in charge and with all staff pharmacists to ensure the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy. The pharmacy, by and through its owner or license holder, shall be responsible for employing a professionally competent, legally qualified pharmacist in charge.

8.3(3) *Pharmacy and pharmacist in charge.* The pharmacist in charge and the pharmacy, by and through its owner or license holder, shall share responsibility for, at a minimum, the following:

a. Ensuring that the pharmacy employs an adequate number of qualified personnel commensurate with the size and scope of services provided by the pharmacy.

b. Ensuring the availability of any equipment and references necessary for the particular practice of pharmacy.

c. Ensuring that there is adequate space within the prescription department or a locked room not accessible to the public for the storage of prescription drugs, including controlled substances, devices, and pharmacy records, and to support the operations of the pharmacy.

8.3(4) *Pharmacist in charge and staff pharmacists.* The pharmacist in charge and staff pharmacists shall share responsibility for, at a minimum, the following:

a. Ensuring that a pharmacist performs prospective drug use review as specified in rule 657—8.21(155A).

b. Ensuring that a pharmacist provides patient counseling as specified in rule 657—6.14(155A).

c. Dispensing drugs to patients, including the packaging, preparation, compounding, and labeling functions performed by pharmacy personnel.

d. Delivering drugs to the patient or the patient's agent.

e. Ensuring that patient medication records are maintained as specified in rule 657—6.13(155A).

f. Training and supervising pharmacist-interns, pharmacy technicians, pharmacy support persons, and other pharmacy employees.

g. Procuring and storing prescription drugs and devices and other products dispensed from the pharmacy.

h. Distributing and disposing of drugs from the pharmacy.

i. Maintaining records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all drugs as required by applicable state and federal laws, rules, and regulations.

j. Ensuring the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy.

8.3(5) *Pharmacy, pharmacist in charge, and staff pharmacists.* The pharmacy, by and through its owner or license holder, the pharmacist in charge, and all staff pharmacists shall share responsibility for, at a minimum, the following:

a. Establishing and periodically reviewing (by the pharmacy and the pharmacist in charge), implementing (by the pharmacist in charge), and complying with (by the pharmacist in charge and staff pharmacists) policies and procedures for all operations of the pharmacy. The policies and procedures shall identify the frequency of review.

b. Establishing and maintaining effective controls against the theft or diversion of prescription drugs, including controlled substances, and records for such drugs.

c. Establishing (by the pharmacy and the pharmacist in charge), implementing (by the pharmacist in charge), and utilizing (by the pharmacist in charge and staff pharmacists) an ongoing, systematic program of continuous quality improvement for achieving performance enhancement and ensuring the quality of pharmaceutical services.

~~**8.3(2)**~~ **8.3(6)** *Practice functions.* The pharmacist is responsible for all functions performed in the practice of pharmacy. The pharmacist maintains responsibility for any and all delegated functions including functions delegated to pharmacist-interns, pharmacy technicians, and pharmacy support persons.

~~**8.3(3)**~~ **8.3(7)** *Pharmacist-documented verification.* The pharmacist shall provide, document, and retain a record of the final verification for the accuracy, validity, completeness, and appropriateness of the patient's prescription or medication order prior to the delivery of the medication to the patient or the patient's representative.

ITEM 9. Amend rule 657—8.5(155A) as follows:

657—8.5(155A) Environment and equipment requirements. There shall be adequate space, equipment, and supplies for the professional and administrative functions of the pharmacy pursuant to rule 657—8.3(155A). Space and equipment in an amount and type to provide secure, environmentally controlled storage of drugs shall be available.

8.5(1) to **8.5(6)** No change.

8.5(7) *Other equipment.* The pharmacist in charge and the pharmacy, by and through its owner or license holder, shall ~~ensure~~ share the responsibility for ensuring the availability of any other equipment

necessary for the particular practice of pharmacy and to meet the needs of the patients served by the pharmacy.

8.5(8) *Bulk counting machines.* Unless bar-code scanning is required and utilized to verify the identity of each stock container of drugs utilized to restock a counting machine cell or bin, a pharmacist shall verify the accuracy of the drugs to be restocked prior to filling the counting machine cell or bin. A record identifying the individual who verified the drugs to be restocked, the individual who restocked the counting machine cell or bin, and the date shall be maintained. ~~The pharmacy~~ Established policies and procedures shall ~~have~~ include a method to calibrate and verify the accuracy of the counting device. ~~and~~ The pharmacy shall, at least quarterly, verify the accuracy of the device and maintain a dated record identifying the individual who performed the quarterly verification.

ITEM 10. Amend rule 657—8.14(155A) as follows:

657—8.14(155A) Training and utilization of pharmacy technicians or pharmacy support persons. ~~All~~ Pursuant to rule 657—8.3(155A), all Iowa-licensed pharmacies utilizing pharmacy technicians or pharmacy support persons shall ~~develop, implement, and periodically review~~ have written policies and procedures for the training and utilization of pharmacy technicians and pharmacy support persons appropriate to the practice of pharmacy at that licensed location. ~~Pharmacy policies shall specify the frequency of review.~~ Pharmacy technician and pharmacy support person training shall be documented and maintained by the pharmacy for the duration of employment. Policies and procedures and documentation of pharmacy technician and pharmacy support person training shall be available for inspection by the board or an agent of the board.

ITEM 11. Amend subrule 8.15(2) as follows:

8.15(2) *Policies and procedures required.* ~~Every~~ Pursuant to rule 657—8.3(155A), every pharmacy shipping or otherwise delivering prescription drugs or devices to Iowa patients shall ~~develop and implement~~ have policies and procedures to ensure accountability, safe delivery, and compliance with temperature requirements as defined by subrule 8.7(4).

ITEM 12. Amend rule 657—8.26(155A) as follows:

657—8.26(155A) Continuous quality improvement program. ~~Each~~ Pursuant to rule 657—8.3(155A), each pharmacy licensed to provide pharmaceutical services to patients in Iowa shall implement or participate in a continuous quality improvement program ~~or~~ (CQI program). The CQI program is intended to be an ongoing, systematic program of standards and procedures to detect, identify, evaluate, and prevent medication errors, thereby improving medication therapy and the quality of patient care. A pharmacy that participates as an active member of a hospital or corporate CQI program that meets the objectives of this rule shall not be required to implement a new program pursuant to this rule.

8.26(1) No change.

8.26(2) *Responsibility.* ~~The pharmacist in charge is responsible for ensuring that the pharmacy utilizes a CQI program consistent with the requirements of this rule.~~ The pharmacist in charge may delegate program administration and monitoring, but the pharmacist in charge maintains ultimate responsibility for the validity and consistency of program activities.

8.26(3) *Policies and procedures.* ~~Each~~ Pursuant to rule 657—8.3(155A), each pharmacy shall ~~develop, implement, and adhere to~~ have written policies and procedures for the operation and management of the pharmacy's CQI program. A copy of the pharmacy's CQI program description and policies and procedures shall be maintained and readily available to all pharmacy personnel. The policies and procedures shall address, at a minimum, a planned process to:

a. to *f.* No change.

8.26(4) to **8.26(6)** No change.

ITEM 13. Amend rule 657—9.3(147,155A) as follows:

657—9.3(147,155A) ~~Pharmacist in charge responsibilities~~ Responsibilities.

9.3(1) *AMDS.* ~~The pharmacist in charge of~~ In any pharmacy utilizing an AMDS, the following responsibilities, which are in addition to the responsibilities required by all applicable federal and state laws, rules and regulations and the responsibilities described in rule 657—8.3(155A), shall be ~~responsible for the following in addition to other responsibilities~~ assigned ~~under federal and state laws and regulations~~ as follows:

a. ~~Implementing~~ The pharmacy and the pharmacist in charge shall share responsibility for establishing, the pharmacist in charge shall be responsible for implementing, and the pharmacist in charge and staff pharmacists shall share responsibility for utilizing an ongoing quality assurance program the purpose of which ~~purpose~~ is to monitor and improve performance of each AMDS as provided in rule 657—9.10(147,155A).

~~*b.* Establishing and ensuring compliance with all policies and procedures relating to the AMDS.~~

~~*c.*~~ *b.* ~~Assigning~~ The pharmacist in charge shall be responsible for assigning, discontinuing, or changing drug and information access to the AMDS.

~~*d.*~~ *c.* The pharmacist in charge and staff pharmacists shall share responsibility for:

(1) Ensuring that drug access, including access to controlled substances, is in compliance with state and federal laws, rules and regulations.

(2) Ensuring that each AMDS component is filled or stocked accurately and in accordance with established, written policies and procedures.

(3) Ensuring that each AMDS component is in good working order and performs its designated tasks, including ensuring the correct strength, dosage form, and quantity of the prescribed drug.

(4) Ensuring that confidentiality of patient-specific information is maintained.

(5) Ensuring that all personnel utilizing or accessing the AMDS or any component of the AMDS have been appropriately trained.

~~*e.* Ensuring that each AMDS component is filled or stocked accurately and in accordance with established, written policies and procedures.~~

~~*f.* Ensuring that each AMDS component is in good working order and performs its designated tasks, including ensuring the correct strength, dosage form, and quantity of the prescribed drug.~~

~~*g.*~~ *d.* ~~Ensuring~~ The pharmacy, by and through its owner or license holder, pharmacist in charge, and staff pharmacists shall share responsibility for ensuring that the AMDS has adequate security safeguards regarding drug ~~access~~ and information access.

~~*h.* Ensuring that confidentiality of patient-specific information is maintained.~~

~~*i.* Ensuring that all personnel utilizing or accessing the AMDS or any component of the AMDS have been appropriately trained.~~

~~*j.*~~ *e.* ~~Ensuring that the board is provided~~ The pharmacy shall provide the board with written notice at least 30 days prior to an installation, removal, or upgrade that significantly changes the operation of an AMDS. The notice shall include:

(1) to (6) No change.

9.3(2) No change.

ITEM 14. Amend rule 657—9.10(147,155A) as follows:

657—9.10(147,155A) Quality assurance and performance improvement. The goal of any AMDS is the accurate dispensing of drugs. In all dispensing activities, the pharmacy shall strive for 100 percent accuracy. Quality assurance data shall be utilized to monitor and improve systems.

9.10(1) *AMDS.* Pharmacies utilizing an AMDS shall ~~develop~~ have a written quality assurance and monitoring plan pursuant to rule 657—9.3(147,155A) prior to implementation of the AMDS. The quality assurance plan shall target the preparation, delivery, and verification of AMDS unit contents during fill and refill processes and shall include, but not be limited to, the following:

a. to *d.* No change.

9.10(2) to **9.10(4)** No change.

ITEM 15. Amend rule 657—9.11(147,155A) as follows:

657—9.11(147,155A) Policies and procedures. Notwithstanding rule 657—8.3(155A), policies and procedures for an AMDS shall be required pursuant to this chapter. All policies and procedures shall be in writing and shall be maintained in the pharmacy responsible for the AMDS or, if a telepharmacy practice, shall be maintained at both the managing pharmacy and the remote site. All policies and procedures shall be reviewed at least annually and revised as necessary, and the review shall be documented. Additions, deletions, amendments, and other changes to policies and procedures shall be signed or initialed by the pharmacist in charge, shall include the date on which the change was approved, and shall be maintained for a minimum of two years following the date of the change. The policy and procedure manual and retained changes shall be available for inspection and copying by the board or an agent of the board.

9.11(1) *AMDS.* ~~All pharmacies utilizing AMDS shall develop, implement, and adhere to policies and procedures that address~~ Pursuant to rule 657—8.3(155A) and this chapter, a pharmacy shall have policies and procedures for an AMDS that provide, at a minimum, the following:

a. to *k.* No change.

9.11(2) No change.

ITEM 16. Amend rule 657—15.3(155A) as follows:

657—15.3(155A) ~~Pharmacist in charge~~ Responsibilities. ~~One professionally competent, legally qualified pharmacist who is licensed to practice pharmacy in Iowa shall be the pharmacist in charge of the~~ In any correctional pharmacy ~~and~~, the following responsibilities, which are in addition to the responsibilities required by all applicable federal and state laws, rules and regulations and the responsibilities as described in rule 657—8.3(155A), shall be ~~responsible for, at a minimum, the following~~ assigned as follows:

~~1. Ensuring that the pharmacy utilizes an ongoing, systematic program for achieving performance improvement and ensuring the quality of pharmaceutical services;~~

~~2. Ensuring that the pharmacy employs an adequate number of qualified personnel commensurate with the size and scope of services provided by the pharmacy;~~

~~3.~~ 1. ~~Ensuring~~ The pharmacist in charge or designee shall ensure that a quarterly inspection of all pharmaceuticals located at the correctional facility, including any emergency/first dose drug supply located outside the confines of the pharmacy, is completed and documented~~;~~.

~~4. Ensuring the availability of any equipment and references necessary for the particular practice of pharmacy;~~

~~5. Preparing written policies and procedures governing pharmacy functions; periodically reviewing and revising those policies and procedures to reflect changes in processes, organization, and other pharmacy functions; ensuring that policies and procedures are consistent with board rules; and ensuring that all pharmacy personnel are familiar with the policies and procedures;~~

~~6. Ensuring that a pharmacist performs prospective drug use reviews as specified in rule 657—8.21(155A);~~

~~7.~~ 2. ~~Ensuring that~~ The pharmacist in charge or a pharmacist ~~provides~~ shall provide drug information to other health professionals, to other caregivers, and to patients as required or requested~~;~~.

~~8. Dispensing drugs to patients, including the packaging, preparation, compounding, and labeling functions performed by pharmacy personnel;~~

~~9. Delivering drugs to the patient or the patient's agent;~~

~~10. Ensuring that patient drug records are maintained as specified in rule 657—15.8(124,126,155A);~~

~~11. Training pharmacy technicians and pharmacy support persons;~~

~~12. Establishing policies and procedures for the procurement and storage of prescription drugs and devices and other products dispensed from the pharmacy;~~

~~13. Disposing of and distributing drugs from the pharmacy;~~

~~14. Maintaining records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all drugs as required by applicable state and federal laws, rules, and regulations;~~

~~15. Establishing and maintaining effective controls against the theft or diversion of prescription drugs and records for such drugs;~~

~~16. Ensuring the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy.~~

ITEM 17. Amend subrule 15.5(2) as follows:

15.5(2) *Access when pharmacist absent.* ~~The pharmacist in charge, with the concurrence of the department, shall establish and implement~~ Pursuant to rule 657—8.3(155A), the pharmacy shall have policies and procedures for the security of the correctional pharmacy. Policies and procedures shall identify who will have access to the pharmacy, what areas may be accessed, and the procedures to be followed for obtaining drugs and chemicals when the pharmacist is absent from the pharmacy.

ITEM 18. Amend rule 657—15.7(124,126,155A) as follows:

657—15.7(124,126,155A) Training and utilization of pharmacy technicians or pharmacy support persons. ~~All correctional pharmacies utilizing pharmacy technicians or pharmacy support persons shall develop, implement, and periodically review written policies and procedures for the training and utilization of pharmacy technicians and pharmacy support persons appropriate to the practice of pharmacy at that licensed location. Pharmacy policies shall specify the frequency of the review.~~ Pharmacy technician and pharmacy support person training shall be documented and maintained by the pharmacy for the duration of employment. Policies and procedures and documentation of pharmacy technician and pharmacy support person training shall be available for inspection by the board or an agent of the board.

ITEM 19. Amend rule 657—15.10(124,126,155A) as follows:

657—15.10(124,126,155A) Policies and procedures. ~~The pharmacist in charge shall develop and implement written policies and procedures for the pharmacy drug distribution system consistent with board rules and department policies and procedures pertaining to pharmaceutical services.~~ Pharmacy policies and procedures, established, implemented, and complied with pursuant to rule 657—8.3(155A), shall address, but not be limited to, the following:

1. to 22. No change.

ITEM 20. Amend rule 657—18.10(155A) as follows:

657—18.10(155A) Policy and procedures.

18.10(1) *Manual maintained.* ~~A~~ Pursuant to rule 657—8.3(155A), a policy and procedure manual relating to centralized filling or centralized processing activities shall be maintained at all pharmacies involved in centralized filling or centralized processing and shall be available for inspection and copying by the board or an agent of the board.

18.10(2) No change.

ITEM 21. Amend rule 657—19.7(155A) as follows:

657—19.7(155A) Confidential data. ~~The pharmacist in charge shall be responsible for developing, implementing, and enforcing~~ Pursuant to rule 657—8.3(155A), each nonresident pharmacy shall have policies and procedures to ensure patient confidentiality and to protect patient identity and patient-specific information from inappropriate or nonessential access, use, or distribution pursuant to the requirements of 657—8.16(124,155A).

ITEM 22. Amend rule 657—19.8(124,155A) as follows:

657—19.8(124,155A) Storage and shipment of drugs and devices. ~~The pharmacist in charge shall be responsible for developing, implementing, and enforcing~~ Pursuant to rule 657—8.3(155A), each nonresident pharmacy shall have policies and procedures to ensure compliance with rules 657—8.7(155A) and 657—8.15(155A) and USP standards for the storage and shipment of drugs and devices. Policies and procedures shall provide for the shipment of controlled substances via a secure and traceable method, and all records of such shipment and delivery to Iowa patients shall be maintained for a minimum of two years from date of delivery.

ITEM 23. Amend rule 657—19.9(155A) as follows:

657—19.9(155A) Patient record system, prospective drug use review, and patient counseling.

19.9(1) and **19.9(2)** No change.

19.9(3) *Patient counseling.* ~~The pharmacist in charge shall be responsible for developing, implementing, and enforcing~~ Pursuant to rule 657—8.3(155A), each nonresident pharmacy shall have policies and procedures to ensure that Iowa patients receive appropriate counseling pursuant to the requirements of rule 657—6.14(155A).

ITEM 24. Amend subrule 22.7(6) as follows:

22.7(6) *Notifications.* Whenever an emergency/first dose drug supply is opened or has expired, the provider pharmacy shall be notified and the pharmacist shall be responsible for replacing the drug within 72 hours to prevent risk of harm to patients. ~~Policy must be developed by the provider pharmacist to~~ Pursuant to rule 657—8.3(155A), established policies and procedures shall address notification, record keeping, and documentation procedures for use of the supply.

ITEM 25. Amend subrule 22.7(7) as follows:

22.7(7) *Procedures.*

a. ~~The consultant or provider pharmacist~~ The pharmacy shall, in communication with the director of nursing of the facility and the medical director of the facility, or their respective designees, ~~develop and implement~~ and as provided in rule 657—8.3(155A), have written policies and procedures to ensure compliance with this rule.

b. to *d.* No change.

ITEM 26. Amend subrule 22.9(6) as follows:

22.9(6) *Policies and procedures.* ~~The pharmacist in charge of the provider pharmacy and~~ The pharmacy, pursuant to rule 657—8.3(155A) and in coordination with the home health agency or hospice, shall ~~develop~~ have policies and procedures to address storage conditions and security for drugs and kit maintenance. Outdated, expired drugs shall be properly disposed of by the pharmacy.

ITEM 27. Amend subrule 22.9(7) as follows:

22.9(7) *Responsibility for compliance.* ~~The provider pharmacy is responsible to ensure~~ The pharmacist in charge and staff pharmacists shall share responsibility for compliance with this rule, and any abuse or misuse of the intent of this rule shall be immediately reported to the board.

ITEM 28. Amend rule 657—23.4(124,155A) as follows:

657—23.4(124,155A) ~~Pharmacy responsibilities~~ Responsibilities. The ~~long-term care pharmacy~~ pharmacist in charge and staff pharmacists in any pharmacy providing pharmaceutical services to long-term care facility patients shall ~~be responsible~~ share responsibility for:

1. to 4. No change.

5. ~~Developing~~ Complying with a drug recall procedure, established pursuant to rule 657—8.3(155A), that protects the health and safety of residents including immediate discontinuation of any recalled drug or device and subsequent notification of the prescriber and director of nursing of the facility.

6. Providing ~~a~~ 24-hour emergency service ~~procedure~~ either directly or by contract with another pharmacy.

7. to 9. No change.

ITEM 29. Amend rule 657—23.6(124,155A) as follows:

657—23.6(124,155A) Space, equipment, and supplies. ~~Each~~ Pursuant to rule 657—8.3(155A), each pharmacy serving a long-term care facility shall have adequate space, equipment, and supplies for the professional and administrative functions of the pharmacy and to meet the needs of the residents served. The pharmacy shall also comply with all reference, environment, and equipment requirements contained in rules 657—6.3(155A) and 657—8.5(155A).

ITEM 30. Amend rule 657—23.7(124,155A) as follows:

657—23.7(124,155A) Policies and procedures. ~~Policies and procedures shall be formulated to cover the provider~~ Pursuant to rule 657—8.3(155A), each pharmacy shall have policies and procedures related to all aspects of the pharmacy's packaging and dispensing responsibilities to the residents of the long-term care facility. The policies and procedures shall be maintained at the provider pharmacy and shall be available to the facility and the consultant pharmacist. Policies and procedures shall include, at a minimum:

1. to 4. No change.

ITEM 31. Amend rule 657—23.10(124,155A) as follows:

657—23.10(124,155A) Stop orders. ~~The consultant pharmacist, in consultation with the provider pharmacist, the medical director, and the appropriate committee or representative of the facility, shall develop and implement an automatic stop order policy.~~ To ensure that drug orders are not continued inappropriately, ~~drugs~~ the pharmacy's policies and procedures, established pursuant to rule 657—8.3(155A) and in consultation with the medical director and the appropriate committee or representative of the facility, shall include an automatic stop order policy. Drugs not specifically limited when ordered as to duration of therapy or number of doses shall be controlled by the automatic stop order policy in accordance with the status of the patient.

ITEM 32. Amend subrule 23.13(4) as follows:

23.13(4) *Leave meds.* Labeling of prescription drugs for residents on leave from the facility for a period in excess of 24 hours shall comply with 657—subrule 6.10(1). The dispensing ~~pharmacy~~ pharmacist shall be responsible for packaging and labeling leave meds in compliance with this subrule.

ITEM 33. Amend subrule 23.13(5) as follows:

23.13(5) *Discharge meds.* Drugs authorized for a resident being discharged from the facility shall be labeled in compliance with 657—subrule 6.10(1) before the resident removes those drugs from the facility premises. The dispensing ~~pharmacy~~ pharmacist shall be responsible for packaging and labeling discharge meds in compliance with this subrule.

ITEM 34. Amend rule 657—23.16(124,155A) as follows:

657—23.16(124,155A) Destruction of outdated and improperly labeled drugs. ~~The consultant pharmacist, in consultation with the provider pharmacist and a facility representative, shall develop and implement~~ The pharmacy shall, pursuant to rule 657—8.3(155A) and in consultation with a facility representative, have written policies and procedures to ensure that all discontinued, outdated, deteriorated, or improperly labeled drugs and all containers with worn, illegible or missing labels are destroyed or disposed of so as to render them unusable. Drugs shall be destroyed by means that will ensure protection against unauthorized possession or use.